REMARKS

The Examiner points out that the abstract is missing. The above amendment amends the specification by adding a new page 22 following the claims, which contains the abstract as filed with the priority application, US appl. SN 60/458,782. It is respectfully requested that the Examiner approve the entry of the abstract.

Claims 1, 3, 4, and 6-8 were rejected under 35 U.S.C. §102(e) as being anticipated by US application publication no. 2004/0097806 (Hunter). Claim 1 has been amended to more clearly define the present invention. Amended Claim 1 describes a method of producing a three dimensional ultrasonic image containing spatial information of the placement or operation of an invasive medical device comprising acquiring real time three dimensional ultrasonic image data with a two dimensional array transducer from a volumetric region containing an invasive medical device; volume rendering the three dimensional ultrasonic image data to produce a sequence of real time three dimensional ultrasonic images; transmitting the three dimensional ultrasonic images to an interventional system; converting the three dimensional ultrasonic images and position or image data of the interventional system to a common frame of reference; aligning the three dimensional ultrasonic images with position or image data of the invasive medical device; and combining the position or image data of the invasive medical device with the three dimensional ultrasonic images of the real time sequence of images. The present invention enables an interventional device procedure to be monitored in real time by observing the interventional device in real time 3D ultrasonic images. FIGURE 7 shows an EP probe 30 being imaged in 3D in real time as an electrophysiology procedure is being performed with the tip of the probe 32 periodically contacting the wall of the beating heart. Since a beating heart is always in motion and it is important to contact the heart wall in exactly the right location to resynchronize heart motion, it is important to be able to observe the probe in the heart in real time. A static image will not do. Accordingly the present invention enables 3D ultrasonic guidance of sensitive invasive procedures without the risk of ionizing radiation.

Hunter describes a complex system which is designed to properly place an icon representing the location of a catheter on a 2D ultrasound image. A C-arm x-ray system captures x-ray images and stores the images for later use (see paragraph [0034]). A navigation system 10 generates electromagnetic fields within the patient, and produces a translation map which is used by the C-arm system to identify the point where the catheter is present on a pre-acquired image (see paragraph [0049]). An icon representing the location

of the catheter is then superimposed over the pre-acquired images (see paragraph [0058]). While the application mentions 3D in paragraph [0039], it is seen that this is to use images of more than one plane in which to show the catheter icon. The catheter icon is not displayed in a 3D ultrasound image or any other 3D image.

Since the Hunter system does not produce live (real time) 3D ultrasound images, it is impossible to follow the procedure performed by the catheter in real time. For procedures where the anatomy is moving, Hunter proposes in paragraph [0056] to acquire gated images. Thus, each image will have the same relation to the phase of the heart cycle such as end diastole. If the heart moves, Hunter suggests acquiring another gated image and updating the image that is shown on the display.

Since Hunter only uses 2D images, the catheter may or may not be in the image plane currently being displayed. It is for this reason that Hunter has a CATHETER VISIBLE step in his flowchart of FIGURE 3, for the system has to constantly check whether the catheter is in the current image plane and can be displayed. This problem is not present with 3D ultrasound images in the present invention, since the volume imaged can extend on all sides of the invasive device, constantly keeping it in view during the entire invasive procedure.

To highlight these differences in Claim 1, the claim has been amended to recite that real time ultrasonic image data is acquired, which is volume rendered to produce a sequence of real time three dimensional images as stated on pages 6 and 14 of the specification. Acquisition is done with a two dimensional array transducer as recited on page 7, which provides fully electronic 3D image acquisition and is not shown or suggested by any of the citations. The position or image data of an invasive medical device is combined with the three dimensional ultrasonic images to produce a real time sequence of 3D ultrasound images that enable a clinician to follow the procedure in real time. For these reasons it is respectfully submitted that amended Claim 1 and its dependent Claims 2 and 3 are not anticipated by Hunter.

Claim 4 describes a method of producing a three dimensional ultrasonic image containing spatial information of the placement or operation of an invasive medical device comprising acquiring a three dimensional ultrasonic image data set from a volumetric region containing an invasive medical device; scan converting the three dimensional ultrasonic image data set; transmitting the scan converted three dimensional ultrasonic image data set to an interventional system; converting the three dimensional ultrasonic image data set to a frame of reference of the interventional system; combining the three dimensional ultrasonic

image data set with position or image data of the invasive medical device; and volume rendering the combined data to produce a composite three dimensional image. Claim 4 describes a method of producing a 3D ultrasound image which is not shown or suggested by Hunter or any other citation. The 3D ultrasound image data is acquired and scan converted. Then it is transmitted to an interventional system where the 3D ultrasound image data is converted to a frame of reference of the interventional system. After the position or image data of the interventional system is combined with the 3D ultrasound image data, the combination is volume rendered to produce a composite 3D image of both the anatomy shown in the ultrasound image and the location of the invasive device. Thus, volume rendering is only done once, at the end, after the data of the two systems has been aligned and combined.

Hunter does not even use the word "rendering." This is understandable, because Hunter is only working with 2D images. Accordingly it is respectfully submitted that Hunter cannot anticipate Claim 4 or its dependent Claims 5 and 6.

Claim 7 describes a method of producing a three dimensional ultrasonic image containing spatial information of the placement or operation of an invasive medical device comprising transmitting position or image data of an invasive medical device to an ultrasonic imaging system; converting the device position or image data to a frame of reference of the ultrasonic imaging system; acquiring a three dimensional ultrasonic image data set from a volumetric region containing the invasive medical device; scan converting the three dimensional ultrasonic image data set; combining the scan converted three dimensional ultrasonic image data set with the position or image data of the invasive medical device; and volume rendering the combined data to produce a composite three dimensional image. In this method the data of the invasive device is transmitted to the ultrasound system, where it is converted to a common frame of reference with the 3D ultrasound image data, then the two are combined after the ultrasound image data is scan converted. The combined data is then volume rendered to produce a composite 3D image of the volume scanned by the ultrasound image and the invasive device. As previously mentioned, Hunter does not even use the word "rendering" in his application. Accordingly it is respectfully submitted that Hunter cannot anticipate Claim 7 or its dependent Claim 8.

Claims 2 and 5 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hunter in view of US Pat. 6,256,529 (Holupka). Holupka uses a conventional mechanical probe from Kretz Corp. as stated in col. 4, line 48 to col. 5, line 14. This probe is used to collect a series of 2D images of the prostate as stated at col. 5, lines 50-51. This scan is

done before the actual implant as stated at col. 7, lines 24-25 and is used to plan the therapy and the positions where the radioactive seeds are to be implanted. During the actual implant the probe is used to view the seeds and the needles 19 used for implant in the ultrasound image as stated at col. 7, lines 56-59. As the needles are inserted into the patient, they will appear in the image volume and hence are reconstructed in the VR reconstruction. Thus, only a single image is produced, the one from the ultrasound probe, which is used to view the needles as they are inserted. Unlike Claim 1, there is no two dimensional array transducer used to acquire ultrasound image data. There is no image or position data provided by the needles or seeds as called for by Claim 1, and there is no combining of position or image data of the needles or seeds with three dimensional ultrasonic images as recited in the claim. There is also no acquisition of transducer position information as recited in Claim 2. Thus, the combination of Hunter and Holupka cannot render Claim 1 unpatentable, nor its dependent Claim 2.

Since the needles and seeds of Holupka do not provide any position or image data, there can be no combining of three dimensional ultrasonic image data with position or image data of the invasive medical device as recited in Claim 4. There can thus be no volume rendering of combined data as called for by Claim 4. As previously mentioned, Hunter does not mention volume rendering at all since Hunter works with two dimensional x-ray images from a C-arm. There is also no acquisition of transducer position information of the Holupka probe as called for in Claim 5. For these reasons it is respectfully submitted that the combination of Hunter and Holupka cannot render Claim 4 or its dependent Claim 5 unpatentable.

Claims 9-12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hunter in view of US Pat. 6,515,657 (Zanelli). Amended Claim 9 describes a method of producing a three dimensional ultrasonic image containing spatial information of the placement or operation of an invasive medical device comprising transmitting volume rendered video data from an interventional system to an ultrasonic imaging system; acquiring a three dimensional ultrasonic image data set from a volumetric region containing an invasive medical device; scaling and orienting the three dimensional ultrasonic image data set and the volume rendered data from the interventional system to a common frame of reference; volume rendering the three dimensional ultrasonic image data set to produce a three dimensional ultrasonic image; and combining the interventional system video data and the three dimensional ultrasonic image. This method has an ultrasound system receive volume rendered data from an interventional system. The ultrasound system acquired a

three dimensional ultrasound image which is volume rendered separately. The scaling of the two volume renderings is aligned and both sets of volume rendered data are combine to form a composite of the ultrasound image of the anatomy with the interventional system data. Thus, both data sets are separately rendered, then aligned and combined. As previously mentioned, Hunter does not mention volume rendering since Hunter is working with 2D x-ray images, so there is no volume rendering of any data set in Hunter's system. In Hunter an icon representing the catheter is simply superimposed over a pre-acquired x-ray image from the C-arm. See Hunter at paragraph [0058]. Likewise, Zanelli does not perform volume rendering. Zanelli acquires 3D image data, then projects it to a 2D projection image. See Zanelli at col. 9, lines 5-7. The preferred projection planes are RAO and LAO projections. See col. 5 at lines 27-30. An ultrasound probe is used to acquire the projection image data for the anatomical projection, P(u,v), and the same probe is used to acquire data for a projection image $P_c(u,v)$ of the catheter. See col. 10 at lines 33-36. Thus, there is no image data produced by an interventional device in Zanelli. Zanelli's catheter projection image $P_c(u,v)$ is then superimposed over the anatomical projection image P(u,v). See col. 11 at lines 6-8. Since there is no volume rendering of any image data in either Zanelli or Hunter, it is respectfully submitted that the combination of these two patents cannot render Claim 9 and its dependent Claim 10 unpatentable.

The method of Claim 11 is similar to that of Claim 9, except that volume rendered ultrasound data is transmitted to the interventional system, where the data is scaled and oriented to interventional data which is also volume rendered, and the two volume renderings combined. Since, as just mentioned, there is no volume rendering of any image data in either Zanelli or Hunter, it is respectfully submitted that the combination of these two patents cannot render Claim 11 and its dependent Claim 12 unpatentable. Additionally, Claim 12 recites that the combined volume rendering is done in real time. Zanelli acknowledges that his projection images cannot be done in real time. See col. 10, lines 2-3. Since neither Hunter nor Zanelli produce 3D images in real time, Claim 12 is patentable over these two patents for this further reason.

The Examiner's presumption that the subject matter of the various claims has been commonly owned at all relevant times is correct.

In view of the foregoing amendments and remarks, it is respectfully submitted that the abstract is now present, Claims 1, 3, 4, and 6-8 are not anticipated by Hunter, and that Claims 2, 5, and 9-12 are patentable over any combination of Hunter, Holupka, and Zanelli.

Accordingly it is respectfully requested that the rejection of Claims 1, 3, 4, and 6-8 under 35 U.S.C. §102(e) and of Claims 2, 5, and 9-12 under 35 U.S.C. §103(a) be withdrawn.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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